

To: Sylvie Connors[sconnors@biomedomics.com]; Kent Lupino[klupino@biomedomics.com]
Cc: Brad Heidinger[bheidinger@biomedomics.com]
From: Emma Qiu[/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP
(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3817F734CFA24B918F9BFDCBDF3E6121-CQIU]
Sent: Tue 6/9/2020 4:19:06 PM (UTC-04:00)
Subject: RE: PCO 20-020 and PCO 20-028

[Labeling Variations 060920.pdf](#)

Attached please find the 3 labeling variations we will have with the Gen 2 product. We really need to finalize our labeling variations and REF numbers, can we talk about this tomorrow at the management meeting?

@Kent Lupino do you know if it's at all possible to have US and CE use the same labels? Thanks!

-Emma

From: Sylvie Connors <sconnors@biomedomics.com>
Sent: Tuesday, June 9, 2020 10:43 AM
To: Emma Qiu <cqiu@biomedomics.com>; Kent Lupino <klupino@biomedomics.com>
Cc: Brad Heidinger <bheidinger@biomedomics.com>
Subject: RE: PCO 20-020 and PCO 20-028

Team~

If the 51-003-20 labels haven't been used yet, is there any reason we can't retract them from use along with the 51-003 REF and just update 51-002 to include the kit variation indicators?

Sylvie J. Connors

Sr. QA Associate



From: Emma Qiu <cqiu@biomedomics.com>
Sent: Tuesday, June 9, 2020 10:08 AM
To: Sylvie Connors <sconnors@biomedomics.com>; Kent Lupino <klupino@biomedomics.com>
Subject: PCO 20-020 and PCO 20-028

Hi Sylvie and Kent,

I've managed to find out what happened to the 2-30°C 51-002-20 and 51-003-20 labels after they were informally distributed to Medomics.

For 51-002-20 labels (PCO 20-028): they were applied to 1.4M BD US tests, I've included the lot list in the PCO as an attachment
For 51-003-20 labels (PCO 20-020): even though they were sent to Medomics, they have not used them in production, so I think we can pass this PCO off as the initial distribution of these labels to Medomics.

@Kent Lupino if you can fill in the reason why the back labels are released, these PCO's can be circulated for review and closed.
Thanks!

Best Regards,

Emma Qiu, MS, ASQ Certified Quality Engineer

Product Quality Engineer

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cqiu@biomedomics.com

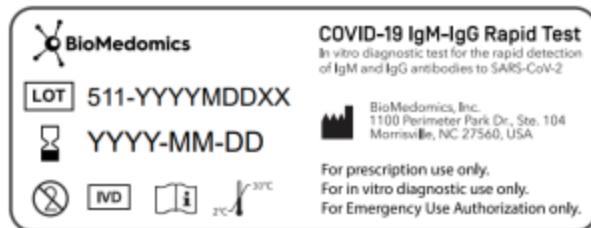
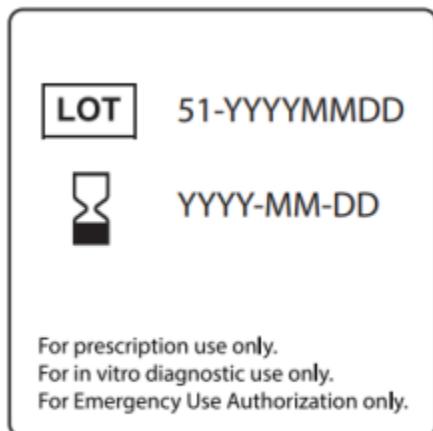


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Morrisville, NC 27560

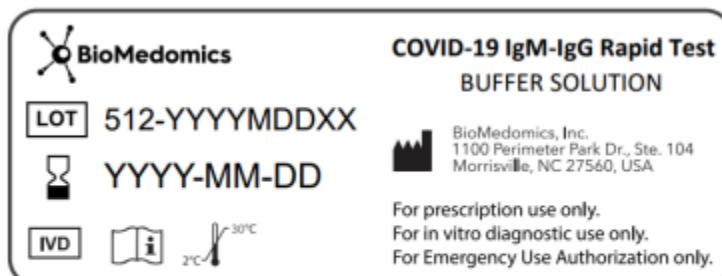
www.biomedomics.com

Labels for BD US (51-002-20) Kits



51-LBL-002-POUCHF-02

51-LBL-002-BACK-01



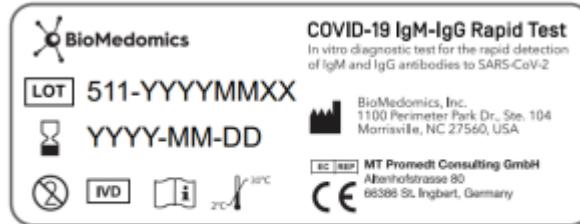
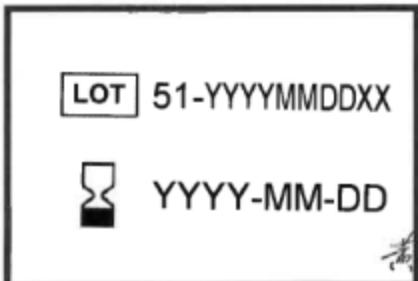
51-LBL-512.US-02

MK1027M0112

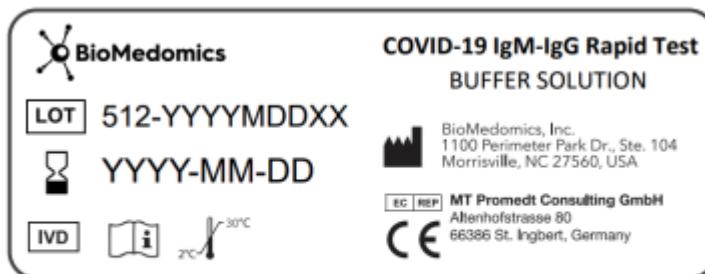


Labels for BD CE (51-003-20) Kits

MK1027M0116



51-LBL-003-POUCHF-02

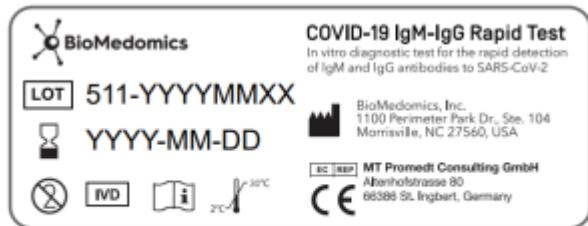


51-LBL-512.EU-02

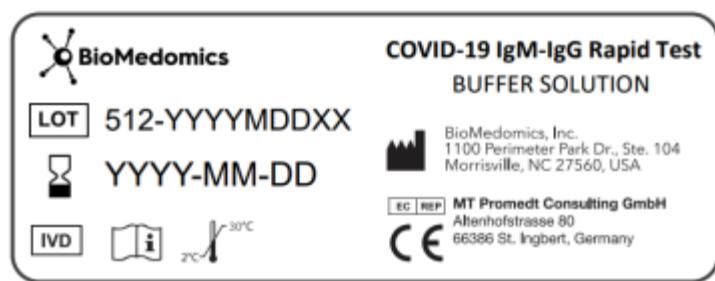
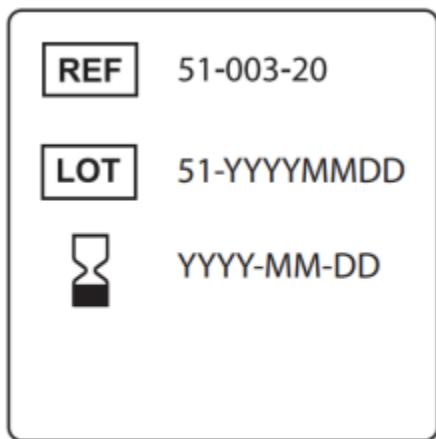
MK1027M0112



Labels for BioMedomics CE (51-003-20) Kits



51-LBL-003-POUCHF-02



51-LBL-512.EU-02

51-LBL-003-BACK-01